and BP Care, despite intending to recover from BP Care. This withdrawal removed any available administrative remedy related to the CMPs and foreclosed any opportunity for BP Care to contest the Survey findings. It also foreclosed any opportunity for BP Care to administratively contest the ALJ's decision to impose successor liability for the CMP.

BP Care filed this action for declaratory and injunctive relief against the Secretary because it had no remedies available at law: it had no statutory or regulatory authorization to intervene or otherwise participate in the Administrative Appeal prior to the withdrawal and it was completely foreclosed from any opportunity to challenge the Survey after the withdrawal. BP Care does not seek monetary reimbursement, or benefits, or payment of funds from the Medicare program, or a determination of whether its Medicare provider agreement has been terminated, or a determination on a denial of Medicare claims submitted by BP Care. Rather, it seeks to be accorded due process and afforded the right to be heard in the proper administrative forum to challenge the administrative remedy being assessed against it by the Secretary, or in the alternative that the Court find that BP Care has no liability for the CMP through the Secretary's waiver, election of remedy, or otherwise through the inapplicability of successor liability under these facts. Since determinations of the Secretary involving non-monetary penalties may be reviewed by the district court (see 42 U.S.C. § 405(g)), the action brought by BP Care is proper.

The Secretary filed a motion to dismiss arguing that BP Care lacked jurisdiction because it failed to exhaust its administrative remedies. The Secretary's position is that BP Care, as assignee of the Medicare provider agreement and through the theory of successor liability, was responsible for the CMP imposed on the bankrupt estate of West Chester.

The district court granted the Secretary's motion, but for slightly different reasons. The court held: (1) that it had no jurisdiction to hear claims arising under the Medicare Act; and (2) that the Secretary has the authority to impose the CMP on BP Care regardless of whether BP Care had access to administrative review.

The Sixth Circuit Court of Appeals affirmed the decision of the district court holding that the district court lacked jurisdiction over BP Care's claims because administrative remedies had not been exhausted.

REASONS WHY THE WRIT SHOULD BE GRANTED

This petition for a writ of certiorari should be granted for the principal reason that the Sixth Circuit's decision conflicts with BP Care's right to due process of law.

I. A Federal Agency May Not Impose Upon a Successor Operator of a Skilled Nursing Facility the Liability of Paying for a CMP Assessed Against the Previous Operator Without According the Successor Due Process of Law.

The Sixth Circuit ultimately concluded that BP Care did not have subject matter jurisdiction because it did not exhaust its administrative remedies. It bases this conclusion upon an uncharacteristically narrow and distorted reading of 42 C.F.R. §§ 488.430-444, the regulations governing the imposition of CMPs upon nursing facilities. The Sixth Circuit inexplicably found that the Secretary is only required to issue a notice of hearing "to a *facility* assessed with CMPs, not to the business operating it. . . . The *facility* has the right either to request a hearing or to waive hearing rights to obtain a

35% reduction in the CMPs." [Emphasis original, citations omitted.] (App. at 19a).

This finding not only runs *contra* to the intent of federal regulations cited, it runs *contra* to every law of business associations known. A physical facility itself, i.e., the "bricks and sticks," is not a legal entity and has no legal capacity. A physical building does not have the capacity to receive a notice of hearing or to request or waive hearing rights. A "facility" cannot act, except through the legal entity that owns or operates it, whether such an owner or operator is a corporation, partnership, limited liability company, sole proprietorship, or other legal entity. Such a holding is akin to finding the motor vehicle, rather than the driver, party to a negligence action arising out of an automobile accident. It simply defies logic.

The Sixth Circuit's interpretation of the term "facility" is inconsistent with the structure of the Medicare Act (42 U.S.C. § 1395), the Medicaid Act (42 U.S.C. § 1396), and the regulations promulgated thereunder. First, for purposes of the relevant regulations the term "facility" is clearly defined as "the entity that participates in the program." 42 C.F.R. § 483.5. Next, the Secretary requires the legal entity operating the facility, i.e., the provider, to enter into a Medicare provider agreement, not the physical facility itself. See 42 C.F.R. § 489.11. If the physical location of the facility was the "provider" to which all rights accrued there would be no reason to require the legal owner to enter into such an agreement. Furthermore, if the physical location of the facility was the "provider," there is no need for federal regulations to recognize the assumption of Medicare provider agreements from one legal owner to another, or the requirement to give notice of a change of ownership or leasing. See 42 C.F.R. § 489.18. There would be no need

to acknowledge a new provider is not required to assume the old Medicare provider agreement, or that a new provider must make ownership disclosures upon a change of ownership. *Id.* In fact, the existence of these rules directly contravenes the premise that the "provider" is the physical location. Why would a new provider agreement be necessary if all rights related thereto attach to the physical location rather than the legal entity? Why would change of ownership rules be necessary at all?

The answer is clear. The provider is the legal entity operating the facility, not the physical location of the facility. The Sixth Circuit decision has taken the responsibility for operating the facility away from the legal owner and placed it upon a fixed location. Will this novel concept hold true for sums owed for settlement audits, post payment reviews, and findings for overpayments as well? When these facilities begin to close because no one wants to assume these newly created liabilities, not only will the Secretary be unable to pursue the old provider (again because it is the "facility" not the provider which gets notice and requests the hearing), but the facilities that close will most likely be those in the most underserved areas, and therefore those residents in the most underserved areas will be injured.

Such a result will have a catastrophic effect on the health care system as a whole as the elderly population in the United States grows with the aging of the baby boomer generation. There already are an estimated 17,000 nursing homes in the United States which currently care for 1.6 million residents – a figure expected to quadruple to 6.6 million residents by 2050. See, 2002, U.S. House of Representatives, Committee on Government Reform-Minority Office. The bankruptcy rate for nursing homes is already alarming. Approximately 1,900 of the 17,000 nursing homes were in bankruptcy in the

year 2000. See, Testimony of Martin Kitchener, Ph.D. and Charlene Harrington, Ph.D., Department of Social and Behavioral Sciences, University of California, San Francisco, To a Joint Informational Hearing of the Senate Health & Human Services Committee and the Senate Subcommittee on Aging and Long Term Care March 6, 2002. Nursing homes in bankruptcy are closing and abandoned. *Id.* The application of the Sixth Circuit's holding will undoubtedly exacerbate this already alarming trend of nursing home closure and abandonment. As the United States Department of Health and Human Services struggles to ensure that the rapidly growing elderly population has access to nursing home services and as providers struggle simply to remain in business, the Sixth Circuit adds more weight to the sinking ship compounding an already dire situation. See, Testimony on Nursing Home Bankruptcies by Steven Pelovitz, Director, Survey and Certification Group, Health Care Financing Administration, U.S. Department of Health and Human Services Before the Senate Special Committee on Aging, September 5, 2000.

The Sixth Circuit simply got it wrong. The administrative rules governing notices and requests for administrative hearings are set forth in 42 C.F.R. Part 498 (governing the appeals process), not, as the Sixth Circuit cited, in 42 C.F.R. Part 488 (governing nursing home surveys in general) or 42 C.F.R. Part 483 (governing the certification requirements of nursing homes in general).

The Sixth Circuit wrongly looks to 42 C.F.R. §§ 488.432 (Civil Money Penalties: When a penalty is collected), 488.434 (Civil Money Penalties: Notice of penalty), 488.436 (Civil Money Penalties: Waiver of hearing, reduction of penalty amount), and 488.438 (Civil Money Penalties: Amount of penalty) (see, App. at 19a) to ascertain BP Care's hearing

rights. Those sections only govern the Secretary's discretionary right to impose CMPs, not a party's right to contest them. The right of a provider to contest any determination of the Secretary is found in 42 C.F.R. Part 498.

Section 42 C.F.R. § 498.32 provides that an *affected party* (not a "facility") is the party given notice of a determination by the Secretary. Section 42 C.F.R. § 498.40 provides that an *affected party* (not the "facility") is the party entitled to request a hearing within 60 days of such a determination. An "*affected party*" is defined as a provider, prospective provider, supplier, prospective supplier or practitioner affected by the Secretary's determination. 42 C.F.R. § 498.2. Only an "*affected party*" who receives notice from the Secretary is entitled to appeal. 42 C.F.R. § 498.5. A "facility" (as the Sixth Circuit envisions it) does not fit any of these definitions.

The sole affected party in this case was West Chester. BP Care never received any notice of a determination that comports with 42 C.F.R. Part 498. Therefore, it was never furnished any due process right to participate in the administrative proceeding.

Moreover, BP Care itself could never have timely requested a hearing (contrary to the Sixth Circuit's Opinion) because the determination upon which the appeal was based clearly preceded BP Care's involvement with the Facility by more than 60 days. West Chester's request for hearing was timely filed on or about April 30, 1999. BP Care did not even become involved until August 1, 1999 - more than 90 days after that. Had BP Care attempted to file a request for hearing at that time the Secretary, by its own regulations and decisions, would have been without jurisdiction to consider it.

See *Nursing Inn of Menlo Park v. CMS*, HHS Departmental Appeals Board, Civil Remedies Division Dec. No. CR799, (July 19, 2001), attached.

To compound this error of law, any right BP Care may have had (assuming it could have been or was made a party to the administrative proceeding) was unilaterally stripped from it when West Chester's Bankruptcy Trustee sent a notice to the ALJ withdrawing the request for a hearing, and the Secretary accepted that withdrawal to the prejudice of BP Care. If BP Care was a party to the administrative proceedings, as the Sixth Circuit's Opinion claims, and if the "facility" is the party with the right to request or waive hearing rights, again as the Opinion claims, how then is a party (i.e., West Chester) who is not the "facility" and has no connection with BP Care, able to file a notice of withdrawal and have that notice effectively terminate everyone else's rights in the Administrative Appeal, including the rights of BP Care and the "facility?" If the status of the Administrative Appeal was as the Sixth Circuit opined, then just because West Chester withdrew itself from the ongoing proceedings does not mean the proceedings should have been terminated as to BP Care (if it is determined to be a party as well) or the "facility." After all, even under the district court's analysis the facility continued to exist and operate. This is where the ALJ, the district court, and the Sixth Circuit erred. Dismissing the Administrative Appeal merely upon West Chester's withdrawal clearly forecloses BP Care's due process protections and raises BP Care's right to proceed in federal court.

II. Since Decisions Involving Non-monetary Penalties Imposed are Reviewed by the District Court (see 42 U.S.C. § 405(g)), the Action Brought by BP Care in the District Court is Proper.

On a more basic level, the Sixth Circuit concluded that the district court did not have jurisdiction to hear BP Care's claims because each of the claims allegedly arose under the Medicare Act and BP Care failed to "present the claims, and exhaust its remedies in an HHS administrative proceeding, as required by 42 U.S.C. §§ 1395ii and 405(h)." (App. at 10a.) This erroneous determination demonstrates the Sixth Circuit's confusion regarding the nature of the claims brought by BP Care. The district court has subject matter jurisdiction to consider this matter pursuant to 28 U.S.C. § 1331.

BP Care's complaint is not a petition for judicial review of an administrative decision. Nor is it an appeal of an administrative decision. There was no administrative hearing and no administrative decision to appeal.

Furthermore, the complaint did not request a review of the underlying nursing home survey and deficiencies that lead to West Chester's CMP. In other words, the complaint did not seek relief on the merits. Rather, it merely seeks declaratory and injunctive relief because BP Care was denied due process of law. It requests the district court to find that the Secretary deprived BP Care of due process by (1) failing to notify BP Care about West Chester's appeal; (2) presuming BP Care was a party to the Administrative Appeal by virtue of the Medicare provider agreement assumed by BP Care when it began operating the Facility (a presumption with which BP Care disagrees), and (3) accepting the Bankruptcy Trustee's notice of withdrawal of the hearing request to the prejudice of BP Care. The complaint further requests that the district

court find – regardless of the underlying merits of the survey and deficiencies – that the Secretary cannot impose successor liability upon a nursing home provider under these circumstances without due process of law. The relief sought is a remand for an administrative hearing.

The holding that BP Care failed to exhaust its administrative remedies and cannot seek judicial review cannot be supported. BP Care was never notified of its right to a hearing and never offered an opportunity to intervene in the existing hearing – even though the Secretary, after notifying the ALJ of the Bankruptcy Case, was ordered to issue notices to all affected parties. BP Care had no access to the Court under 42 U.S.C. §405, and unless it could invoke the federal question jurisdiction under 28 U.S.C. sections 1331, 1343, 1346, 1361, 1651, and/or the United States Constitution, it had no way of obtaining judicial review. See *Ohio Hosp. Assoc. and American Hosp. Assoc. v. Shalala*, 201 F.3d 418 (6th Cir. 2000), and *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986).

The simple fact here is the Secretary imputed another party's liability to BP Care then stripped BP Care of any opportunity to contest that liability. Assuming BP Care is responsible for West Chester's CMP through successor liability, BP Care certainly is entitled to all of West Chester's administrative rights and privileges.

At the time BP Care assumed operation of the Facility, the Administrative Appeal was alive and proceeding. BP Care was not a party to the Administrative Appeal, and was never made a party, despite the ALJ ordering the Secretary to do so. The Secretary, in fact, refused to make BP Care a party.

Moreover, BP Care had no authority to intervene or otherwise join the Administrative Appeal. Unlike the Federal Rules of Civil Procedure, the federal regulations governing this appeal have no provision for intervention or joinder. See 42 C.F.R. 498, *et seq*. Appeal rights are limited to those affected parties described in 42 C.F.R. 498.5. The parties to the hearing are limited to the Secretary and the affected party. 42 C.F.R. § 498.42. Even the Secretary agrees that BP Care does not qualify as an affected party having appeal rights in this matter.

The Secretary's dismissal of the appeal following the Bankruptcy Trustee's notice of withdrawal goes right to the essence of the due process deprivation. BP Care is an independent party. It is not the Bankruptcy Trustee or the Secretary. If BP Care is independently liable for the CMP, any withdrawal by the Trustee should not have affected BP Care's status. But it did. Once the Secretary dismissed the Administrative Appeal upon Bankruptcy Trustee's withdrawal notice, BP Care, having never been made a party to the Appeal, was forever foreclosed from pursuing the underlying Survey findings. BP Care was never furnished the option of subrogation or stepping into the shoes of West Chester to continue the Administrative Appeal. BP Care was never furnished its right to a hearing. Certainly, if BP Care is jointly and severally liable through successor liability for the CMP then the Trustee (a third party) cannot waive liability on behalf of BP Care, and the Secretary was in error to dismiss the appeal. At the least, the Administrative Appeal should have proceeded as to BP Care's liability for the CMP and the underlying findings of noncompliance. Instead, the Secretary dismissed the appeal as to both West Chester and BP Care.

Further, to conclude that BP Care failed to exhaust administrative remedies also is in error because the Secretary,

fully aware of the parties at issue, filed a claim in the Bankruptcy Case and elected to recover the CMP from the Trustee in bankruptcy rather than from BP Care. By filing a claim in the Bankruptcy Case the Secretary made an election of remedies and is now barred from proceeding against BP Care. The doctrine of election of remedies is "the legal version of the idea that a plaintiff may not have his cake and eat it too." *Hickson Corp. v. Norfolk Southern Railway Co.*, 260 F.3d 559, 567 (6th Cir, 2001). The purpose of requiring an election is to prevent a double recovery for a single wrong. *Id.* For example, a party's acceptance of the quantum meruit remedy is inconsistent with the pursuit of its contract claims on appeal. *Tech Hills II Associates v. Phoenix Home Life Mut. Ins. Co.*, 5 F.3d 963 (6th Cir., 1993). The Secretary is entitled to only one recovery here. It cannot seek recovery from BP Care and also hold out for payment from the Bankruptcy Case too. There can only be one provider of a nursing home at a time and the Secretary cannot proceed against two different providers for the same period of time. The Secretary elected to proceed against West Chester in bankruptcy and cannot now proceed against BP Care.

Clearly the district court has subject matter jurisdiction to consider BP Care's request for declaratory judgment and injunctive relief.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: July 28, 2005

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 03-4365

[Filed, May 3, 2005]

BP CARE, INC.,
Plaintiff-Appellant,

v.

TOMMY THOMPSON, Secretary, United States Department of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees.

ORDER

The court having received a petition for rehearing en banc, and the petitio having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel

The panel has further reviewed the petition for rehearing and concludes that the issue raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied

ENTERED BY ORDER OF THE COURT

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 03-4365

[Filed, February 15, 2005]

BP CARE, INC., Plaintiff-Appellant,	)
v.	)
TOMMY THOMPSON, Secretary, United States Department of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants-Appellees.	)

JUDGES: Before: COLE and ROGERS, Circuit Judges; COHN, District Judge.*

* The Honorable Avern Cohn, United States District Judge for the Eastern District of Michigan, sitting by designation

OPINION

ROGERS, Circuit Judge. In this case, BP Care, Inc., contests the Department of Health and Human Services' policy of imposing successor liability for money penalties incurred because of a violation of a Medicare provider agreement. The Department of Health and Human Services assessed civil money penalties ("CMPs") against West Chester Management Company, doing business as Barbara Parke Care Center ("Barbara Parke"), because of inadequate patient care at a nursing home Barbara Parke leased and operated under a Medicare provider agreement. The agency issued Barbara Parke a notice of its right to a hearing to contest the CMPs. Over the ensuing two years, Barbara Parke (1) requested a hearing before an administrative law judge on the charges, (2) ceased operating the facility and assigned its provider agreement to another company, (3) declared bankruptcy, and (4) withdrew its request for a hearing on the CMPs. The Department of Health and Human Services seeks to collect the CMPs from BP Care, the new lessee/operator of the nursing home, under a successor liability theory. BP Care sued in federal district court, alleging that the successor liability scheme violated the Medicare Act's CMP provisions, denied BP Care procedural due process, and constituted arbitrary and capricious agency action under the Administrative Procedure Act. The district court found that it lacked subject-matter jurisdiction over some claims but reached the merits of one: it found that BP Care failed to state a claim in alleging that successor liability for CMPs denied successor Medicare providers due process of law. We affirm, but on different grounds. The district court lacked subject-matter jurisdiction over all of BP Care's claims and therefore should not have reached the due process issue.

I. Background

Barbara Parke operated the nursing home under a lease until August of 1999. In February 1999, a Department of Health and Human Services ("HHS") inspector surveyed the nursing home and found that the facility did not meet Medicare requirements concerning quality of care, quality of life, provision of services, and staff treatment of patients. As Medicare regulations require, HHS served Barbara Parke with a notice of its intent to assess CMPs totaling $35,650.00 on the basis of the deficiencies found in the survey. Regulations require HHS to explain in the notice that the facility has the option of requesting a hearing regarding the CMPs, or accepting the penalty and receiving a thirty-five percent reduction in the amount due. 42 C.F.R. §§ 488.434, 488.436 (2004). On April 30, 1999, Barbara Parke responded to the notice by challenging the validity of each charge and demanding a hearing before an administrative law judge ("ALJ").

In August 1999, Barbara Parke became insolvent and was unable to continue lease payments. Meanwhile, BP Care, Inc., formed on July 16, 1999. The same attorney who represented Barbara Parke in the early stages of the CMP proceedings, Geoffrey Webster, also incorporated and represented BP Care. In August 1999, Barbara Parke assigned both its lease and its Medicare provider agreement to BP Care. Because BP Care used Barbara Parke's Medicare provider number, it was able to continue operating the nursing home without interruption. This continuity, however,

also carried a downside: under HHS policy, BP Care became liable for the outstanding CMPs when it assumed the lease.[1]

BP Care received no communication at this point from HHS notifying BP Care of its potential liability. One month later, on September 13, 1999, Barbara Parke filed for Chapter 11 bankruptcy. It then notified the ALJ charged with conducting the CMP appeal hearing of this development. On October 1, 1999, counsel for the Center for Medicare and Medicaid Services ("CMS")[2] moved the ALJ to stay proceedings on the CMP appeal for ninety days until Barbara Parke decided whether it wished to continue its appeal in light of its bankruptcy. On November 5, 1999, the ALJ, rather than issuing a stay, dismissed and remanded the case to CMS, ordering that CMS "issue a new notice letter to Petitioner" if all new issues were not resolved on remand. The order designated "Barbara Parke Care Center" as the petitioner. The order explained that Barbara Parke's bankruptcy would

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[1] Neither the Medicare Act nor the relevant regulations set forth a policy of successor liability for CMPs. However, both decisions of the HHS Departmental Appeals Board ("DAB") and the HHS State Operations Manual endorse the policy. *See CarePlex of Silver Spring v. Health Care Fin. Admin.*, Docket No. A-98-94, CR536, DAB No. 1683, 1999 WL 985363 (H.H.S.) (Apr. 13, 1999); Centers for Medicare and Medicaid Services, State Operations Manual § 3210E (2004).

[2] The name of this arm of the Department of Health and Human Services changed from Health Care Financing Administration to Centers for Medicare and Medicaid Services while the CMP proceeding was pending. For simplicity, we refer to that office as "CMS."

likely be drawn out, making it difficult for the ALJ to maintain administrative oversight of the case. *Id.*

CMS responded by moving to vacate the order of remand and dismissal. In its motion, CMS signaled for the first time its intent to impose successor liability, stating that a stay of proceeding spending termination of the bankruptcy matter would "not only [delay CMS's] ability to recover any sums from the bankruptcy estate, but . . . also [delay CMS's] ability to exercise its right to recover from [Barbara Parke's] successor, BP Care, Inc., to whom it appears the provider agreement has been automatically assigned." J.A. at 237. CMS served this motion on both Barbara Parke's bankruptcy trustee and BP Care's president. The ALJ granted the motion, reinstating the proceedings before him, on January 22, 2001. In vacating his previous decision to remand to CMS, the ALJ concluded that Barbara Parke's bankruptcy created no new issues in the case, since the bankruptcy did not automatically stay the CMP proceedings, and since CMS was authorized to impose successor liability for the CMPs on BP Care. In May 2001, Barbara Parke's bankruptcy trustee withdrew Barbara Parke's request for a hearing in the CMP proceeding.

Rather than appealing the Secretary's decision to impose CMPs through the narrow means provided in the Medicare and Social Security Acts, *see* 42 U.S.C. §§ 405(h), 1320a-7a(e), 1395ii, BP Care filed this action in the United States District Court for the Southern District of Ohio. The complaint avers that BP Care has no administrative remedy under the Medicare scheme. The complaint asserts jurisdiction under 28 U.S.C. §§ 1331, 1343, 1346, 1361, and 1651. It alleges that, because BP Care was not named as a party in the CMP proceedings and was not served with a right to hearing notice, it was unable to request a hearing regarding imposition of the penalties. Further, the complaint alleges,

HHS's permitting Barbara Parke to withdraw unilaterally its request for a hearing "removed any available administrative remedy related to the CMPs" for BP Care. The complaint asserts that the imposition of CMPs without notice or an opportunity to be heard violates BP Care's procedural due process rights, and also, more generally, that the successor liability concept advanced by HHS violates procedural due process. The complaint alleges that HHS's conduct of the CMP proceedings violated 42 U.S.C. § 1395i-3(h)(2) (the section of the Medicare Act permitting HHS to impose CMPs for substandard performance of Medicare nursing facilities) and was arbitrary and capricious and an abuse of agency discretion in violation of 5 U.S.C. § 706.

The complaint seeks a declaratory judgment and injunction ordering HHS to issue a notice to BP Care affording it the right to a hearing on the CMPs. It prays the court to void the ALJ's January 22, 2001 findings that the automatic stay in bankruptcy did not apply to the CMP proceedings, and that CMS may properly impose successor liability for the CMPs on BP Care. BP Care's parent company, the King Entities, also cross-claimed in Barbara Parke's bankruptcy proceedings, seeking a declaration that any liability for the CMPs be paid out of the bankruptcy estate or paid from an escrow account established at the time of the Barbara Parke-BP Care transaction to cover Medicare overpayments. The district court consolidated that cross-claim with the declaratory judgment action. The Secretary of Health and Human Services moved to dismiss the complaint for lack of jurisdiction and for failure to state a claim.

42 U.S.C. § 405 requires those contesting the decisions of the Commissioner of Social Security to present their claims to the agency and to exhaust avenues of administrative relief before filing an action in federal court. BP Care concedes that

it has not obeyed the strictures of § 405, and that this case is not an appeal of an agency action over which this court would have original jurisdiction. *See* 42 U.S.C. § 1320a-7a(e). Under the narrow reading of *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 90 L. Ed. 2d 623, 106 S. Ct. 2133 (1986), adopted in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 146 L. Ed. 2d 1, 120 S. Ct. 1084 (2000), parties affected by Medicare administrative determinations may sue in federal court under 28 U.S.C. § 1331, bypassing § 405 preclusion, only where requiring agency review pursuant to § 405(h) "would mean no review at all." *Ill. Council*, 529 U.S. at 19. (This concept will be called the *Michigan Academy* exception.) The issue here, therefore, is whether BP Care could have challenged the agency's successor liability scheme administratively.

The district court grouped BP Care's claims into two categories, finding that the first lacked subject-matter jurisdiction and the second failed to state a claim. First, the court addressed BP Care's claim that HHS violated procedural due process by failing to issue BP Care a new "right to hearing" notice and by permitting Barbara Parke unilaterally to withdraw its request for a hearing. The district court found that BP Care could have contested these actions within the administrative process because it was a provider with the right to appeal a hearing decision to the agency's Departmental Appeals Board ("DAB") pursuant to 42 C.F.R. § 498.5. *BP Care v. Thompson*, 337 F. Supp. 2d 1021, 1027 (S.D. Ohio 2003). The court therefore found that this claim "arose under" the Medicare Act and did not form a distinct constitutional claim under the Due Process Clause, and that BP Care was barred from bringing a federal court action rather than exhausting administrative remedies. *Id.* The court also noted that BP Care was served with CMS's motions in the CMP proceedings after it assumed the provider

agreement, and therefore had notice of the proceedings. *Id.* Second, the district court viewed BP Care's challenge to HHS's successor liability scheme as a separate constitutional claim "completely isolated" from BP Care's objections to its treatment in the administrative review process; therefore, the court reached the merits of this claim. *Id.* at 1028. Relying on *Deerbrook Pavilion, LLC v. Shalala,* 235 F.3d 1100 (8th Cir. 2000), the court found that the Medicare Act and regulations authorized successor liability and that BP Care therefore failed to state a claim. *Id.* at 1029. BP Care timely appealed.

II. Jurisdiction Under 28 U.S.C. § 1331

The district court did not have jurisdiction under 28 U.S.C. § 1331 to hear any of BP Care's claims. This is because each of BP Care's claims arises under the Medicare Act, and BP Care failed to present the claims, and exhaust its remedies in an HHS administrative proceeding, as required by 42 U.S.C. §§ 1395ii and 405(h). Under *Illinois Council*, § 405(h) forms the exclusive method for seeking review of claims arising under the Social Security and Medicare Acts. 529 U.S. at 10. The district court correctly dismissed BP Care's first claim for lack of subject-matter jurisdiction, but erred in reaching the merits of the second after concluding that it escaped the stringent jurisdictional bar of § 405(h).

a. Statutory Framework

This conclusion is required by a group of nested jurisdictional provisions that narrowly limits avenues for contesting CMPs assessed for violations of a Medicare provider agreement. Section 1395i-3 of the Social Security Act sets forth substantive requirements for care in Medicare-participating skilled nursing facilities. That section allows

HHS to conduct surveys of nursing homes to determine whether they are compliant, and to impose CMPs for non-compliance. 42 U.S.C. § 1395i-3(h)(2)(B)(ii) (2001). Section 1320a-7a(c) of the same title requires the Secretary to provide notice and an opportunity for a hearing at which the adversely affected person is represented by counsel. A person adversely affected by the Secretary's final determination regarding CMPs may obtain judicial review by suing in a United States Court of Appeals within sixty days after notification of the Secretary's decision. *Id.* § 1320a-7a(e). The person may raise before the reviewing court only those objections voiced in agency administrative proceedings. *Id.* Section 1395ii of the same title makes the jurisdiction-channeling provision of the Social Security Act, *Id.*§ 405(h), applicable to Medicare determinations. That section states, "No findings of factor decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided." *Id.* § 405(h). Section 405 requires both that those challenging agency decisions present their claims to the agency, and that they exhaust administrative remedies before suing in the appropriate federal court. Medicare regulations set forth the exclusive process for contesting CMPs within the agency.

b. Reliance on *Deerbrook Pavilion*

None of the recognized exceptions to § 405(h)'s jurisdictional bar on claims arising under the Medicare Act applies here. In finding jurisdiction over BP Care's challenge to the constitutionality of HHS's successor liability scheme for CMPs, the district court implicitly relied on a case-law exception to § 405(h) that asks whether a claim is "wholly collateral" to the agency action--an exception that the *Illinois Council* case sharply limited. *Illinois Council* read *Michigan Academy* to hold that plaintiffs may sue under 28 U.S.C. §

1331 alleging deficiencies in Medicare adjudicative processes only "where application of § 405(h) . . . would mean no review at all." 529 U.S. at 19. Even though BP Care was liable for the CMPs only as a successor to the Medicare provider agreement, *BP Care* could still have sought agency review of the penalties.

The district court found that *BP Care's* second claim, its challenge to HHS's successor liability policy, was "entirely apart from the proceedings by which the civil money penalty was imposed." *BP Care,* 337 F. Supp. 2d at 1028. Therefore, "the Court may consider the claim as arising under the Due Process Clause within the meaning of 28 U.S.C. § 1331," and 42 U.S.C. § 405(h)'s jurisdictional bar did not apply. *Id.* The district court cited an Eighth Circuit case, *Deerbrook Pavilion, LLC v. Shalala,* 235 F.3d 1100 (8th Cir. 2000), in support of its exercise of jurisdiction. In *Deerbrook*, the only federal court case to assess the constitutionality of successor liability for Medicare CMPs under the Due Process Clause, the Eighth Circuit concluded that *Illinois Council* did not require it to dismiss the plaintiff nursing home's claim for lack of jurisdiction. 235 F.3d at 1103. *Deerbrook* held that the successor's claim did not concern whether its predecessor's conduct warranted CMPs under applicable law, but instead the different question of whether the successor was liable for a prior operator's CMPs. *Id.* Therefore, the lower court in that case had jurisdiction. *Id.*

However, the Eighth Circuit's decision in *Deerbrook Pavilion* does not support the district court's exercise of jurisdiction in this case. First, *Deerbrook Pavilion* is distinguishable, and it may also convey the false impression that Medicare providers may choose whether to press their claims in the first instance in an administrative proceeding or

in a federal court case. The *Deerbrook Pavilion* court stated conclusorily that "it is questionable whether Deerbrook even had the standing (or the incentive) to intervene in contesting the imposition of CMPs on its predecessor." 235 F.3d at 1103. Here, BP Care did have standing to request a hearing. *See infra* Part II.c. The fact that BP Care may not have had *incentive* to participate in the administrative proceeding is irrelevant to the inquiry under *Illinois Council*, which requires that parties seek review of agency action within the administrative setting where possible.

Even more compelling is the manifest tension between the holding of *Deerbrook Pavilion* and the holding of the Supreme Court in *Illinois Council*. The Eighth Circuit in *Deerbrook Pavilion* held that the plaintiff's general objection to HHS's successor liability scheme for CMPs formed a "separate issue" from more specific allegations that a provider's conduct did not warrant CMPs; the latter would be reviewable in an HHS adjudication, while the former was not. 235 F.3d at 1103. *Illinois Council*, however, held that § 405(h)

> forecloses distinctions based upon the "potential future" versus the "actual present" nature of the claim, the "general legal" versus the "fact-specific" nature of the challenge, the "collateral" versus "noncollateral" nature of the issues, or the "declaratory" versus "injunctive" nature of the relief sought. . . . *Claims for money, claims for other benefits, . . . and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, . . . or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions*. There is no reason to distinguish among

> them in terms of the language or in terms of the purposes of § 405(h).

529 U.S. at 13-14 (emphasis added). The Court further noted, "The fact that the agency might not provide a hearing for that *particular contention*, or may lack the power to provide one, . . . is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Id.* at 23. Although ALJs in Medicare administrative proceedings generally do not decide constitutional issues, and although BP Care's challenge to the constitutionality of successor liability is not fact-specific, BP Care's challenge to the successor liability scheme still "arises under" the Medicare Act in that BP Care seeks to avoid an HHS administrative penalty.[3]

By characterizing the factual aspects of a challenge to CMPs as intertwined with the agency adjudication and the

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[3] The facts here are in some respects similar to those of *Mathews v. Eldridge*, 424 U.S. 319, 47 L. Ed. 2d 18, 96 S. Ct. 893 (1976), in that the plaintiff seeks to gain an administrative benefit or to avoid an administrative penalty on the basis of a claim that the agency provided constitutionally deficient procedures. In *Eldridge*, the Court labeled the plaintiff's federal action collateral to his claim for benefits; therefore, the Court found jurisdiction. In *Eldridge*, however, the plaintiff had presented his claim to the agency and pursued *some* avenues of agency review, even though he did not fully exhaust administrative remedies. *Id.* at 326-27. The Court in *Illinois Council* distinguished *Eldridge* from cases in which the plaintiff does not present its challenge to the agency at all. 529 U.S. at 14-15. Presentation of claims is a "nonwaivable and nonexcusable requirement." *Id.* at 15. Here, as in *Illinois Council*, BP Care completely failed to present its claim to the agency.

broader legal aspects of the challenge as separate from the adjudication, the Eighth Circuit in *Deerbrook,* and the district court in this case, relied on the "entirely collateral" exception to § 405(h) preclusion, which *Illinois Council* severely limits.[4] Therefore, unlike the district court, we conclude that *Deerbrook Pavilion* does not dictate a finding that the district court had jurisdiction over BP Care's constitutional challenge to the successor liability scheme.

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[4] The district court opinion does not use the word "collateral," but instead uses the phrases "completely isolated," "entirely apart," and "separate question." 337 F. Supp. 2d at 1028. By rejecting the use of the "entirely collateral" exception here, we do not mean to question this court's assumption in *Cathedral Rock of North College Hill, Inc. v. Shalala,* 223 F.3d 354 (6th Cir. 2000), that the exception survives *Illinois Council* in limited cases. *Id.* at 361-62. *Cathedral Rock*'s holding appears to be limited to cases involving a request for preliminary relief while administrative proceedings are ongoing. The discussion of the "entirely collateral" exception in *Cathedral Rock* recognized at the outset that *Eldridge* "did not create an exception to the application of § 405(g) and (h), but rather required the Secretary to excuse some of its procedural requirements so that its decision would be considered a 'final decision' and judicial review could follow under § 405(g)." *Cathedral Rock*, 223 F.3d at 362 (citing *Ill. Council,* 529 U.S. at 14-15). Here, because BP Care did not present its claims to the agency at all, these cases are inapposite. Moreover, BP Care's complaint seeks remedies that are inextricably intertwined with the CMP administrative proceeding, in that they request the court to nullify findings the ALJ made, or to deny the legal effect of the final action of imposing CMPs on the nursing home.

c. Application of the *Michigan Academy* Exception

In *Illinois Council*, the Supreme Court limited its earlier decision in *Michigan Academy* to hold that § 405(h) applies unless requiring agency review of the plaintiff's claim would effectively mean "no review at all." 529 U.S. at 19. In the context of this case, requiring exhaustion of administrative remedies pursuant to 42 U.S.C. § 405(h) would mean no review of BP Care's claims in only three conceivable situations: (1) if the agency could not consider the subject matter of BP Care's challenge; (2) if BP Care were not a party to the administrative proceedings or lacked standing to intervene in them; or (3) if the procedural posture of the adjudication after Barbara Parke withdrew its request for a hearing made it impossible for BP Care to appeal the CMPs. A review of the regulations governing the Medicare CMP determination for nursing facilities shows that none of these three situations was present in this case.

First, HHS did have the authority to consider the subject matter of BP Care's core challenge--i.e., its claim that it should not be liable for CMPs. In contrast, in *Michigan Academy*, the agency was unable to review the subject matter of the plaintiff's claim, and therefore the application of § 405(h) would have completely denied the plaintiff review. *Michigan Academy* concluded that Congress intended for only *amount determinations* under Part B of the Medicare Act to be subject to agency review, and thus also to the jurisdiction filter of § 405(h). 476 U.S. at 680; *see also Ill. Council*, 529 U.S. at 15-16. Therefore, challenges to the *method* HHS used to compute benefits could form the basis of a separate cause of action in federal court.

Both *Illinois Council* and this case, on the other hand, involve Medicare Part A. The Court held in *Illinois Council*

that *Michigan Academy*'s broad exception to § 405(h) applied only to a situation like that under Medicare Part B, where a category of decisions is not subject to an administrative hearing.[5] *Id.* at 17-18. Here, HHS ALJs may assess both whether CMS properly concluded that the facility was non-compliant and whether CMS therefore properly imposed CMPs, and also whether CMS properly weighed the relevant factors to determine the amount of the CMPs. 42 C.F.R. §§ 488.438(e)-(f), 488.430. When reviewing the amount of CMPs, the ALJ may consider such factors as the facility's degree of culpability, its financial condition, its history of noncompliance, and whether the deficiencies prompting the CMPs are isolated or widespread. *Id.* §§ 488.438 (f), 488.404. BP Care could have participated in Barbara Parke's challenge to the CMPs at the administrative level.[6] Then, it

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[5] Part B of the Act was amended in 1986; under the current law, claimants must pursue administrative challenges to agency's method of determining benefits. *Cathedral Rock*, 223 F.3d at 361 n.3 (citing *Farkas v. Blue Cross & Blue Shield of Mich.*, 24 F.3d 853, 860 (6th Cir. 1994)).

[6] A Departmental Appeals Board case, *CarePlex of Silver Spring v. Health Care Financing Administration*, Docket No. A-98-94, CR536, DAB No. 1683, 1999 WL 985363 (H.H.S.) (Apr. 13, 1999), held that a change of ownership in a facility may form a factor an ALJ considers in deciding whether to decrease the amount of the penalty. In that case, the nursing facility changed hands one week before CMS surveyed it; the new owner invested heavily in improvements, which resulted in a fully compliant facility within two months. The DAB found that presumptively, a history of non-compliance demonstrates a greater likelihood of future violations and thus supports a higher penalty. When a facility has changed hands, however, the new operator may disprove this presumption by making immediate efforts to comply. *CarePlex* suggests that,

could have challenged the constitutional aspects of the fairness of successor liability upon judicial review in a federal appeals court. *See Ill. Council,* 529 U.S. at 23 (noting that the ALJ's lacking the power to consider a particular constitutional argument "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency").

Second, requiring strict adherence to § 405(h) does not effectively preclude review in BP Care's situation because BP Care was a party with standing to contest the money penalties in the agency setting. BP Care argues that it was not the "provider" at the time CMS notified the facility of penalties against it and issued a notice of right to hearing; therefore, it did not have standing to participate in the hearing. Further, BP Care urges that HHS regulations did not provide it with the opportunity to intervene as of right in the proceedings at any point. These contentions appear incorrect.

It is true that in *Buchanan v. Apfel,* 249 F.3d 485 (6th Cir. 2001), this court found a nonparty to agency proceedings to be free of the § 405(h) bar, but that case is inapplicable here. In *Buchanan,* this court addressed an attorney's challenge to the constitutionality of the Social Security Administration's method of awarding legal fees to those who represent claimants. *Id.* at 487. The court found that the

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through participation in an agency hearing, BP Care could have made arguments based on the change in ownership to achieve a substantial reduction in the penalties. *See Id; Crestview Parke Care Ctr. v. Thompson,* 373 F.3d 743, 757 (6th Cir. 2004). Further, BP Care could have sought to demonstrate that the facility was compliant when surveyed, and that the CMPs were therefore erroneously assessed.

Michigan Academy exception applied to the challenge, in part because "the language of § 405(h) indicates that Congress never contemplated a situation where someone other than a party pursuing entitlement benefits would seek review" of a constitutional claim under the Social Security Act. *Id.* at 490. Because the plaintiff, as counsel to a claimant, was not a party withstanding to protest the administrative decision, § 405(h) did not bar his claim.

Buchanan is inapposite here because BP Care was a party to the agency proceedings. HHS regulations require CMS to issue a notice of right to hearing to a *facility* assessed with CMPs, not to the business operating it. 42 C.F.R. § 488.434; *see also id.* (defining "facility"). The *facility* has the right either to request a hearing or to waive hearing rights to obtain a 35% reduction in the CMPs. *Id.* §§ 488.432(a), 488.436. At the hearing, the ALJ may consider the *facility's* financial condition, compliance history, and culpability--not that of the specific business upon which CMS served its initial notice of hearing. *Id.* § 488.438(e), (f). The hearing itself is open to "the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper." *Id.* § 498.60(a). Parties to the hearings are defined as "the affected party[7] and CMS or the OIG." *Id.*

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[7] Medicare regulations do not state whether more than one provider may be "the affected party" in the adjudication. The Secretary on appeal argues not only that HHS imposes successor liability on businesses assuming a previous operator's provider agreement, but also that the predecessor and the successor are jointly and severally liable for CMPs. The regulations do not provide explicitly for either successor liability or joint and several liability for predecessor and successor organizations under a Medicare provider agreement. Given the significant financial liabilities at stake and the risk of sham provider agreement transfers to avoid CMPs if the successor

§ 498.42. The "affected party," unsurprisingly, is a provider affected by CMS's initial determination. *Id.* § 498.42. Thus, the regulations define parties to the administrative proceedings functionally, with respect to their stake in the outcome; they do not define them formally, with respect to whether the provider seeking to participate is the same one served with a notice of right to hearing.

Nonetheless, BP Care would arguably not be a party if it did not know that it was "affected"--i.e., if it had no notice of HHS's practice of imposing successor liability for CMPs. The district court did not commit clear error when it concluded, however, on the basis of the administrative record, that BP Care was served with motions filed by CMS in the CMP proceedings.[8] 337 F. Supp. 2d at 1027. These motions were served as early as January 9, 2000--sixteen months before the matter was terminated by Barbara Parke's withdrawal of its hearing request--and they disclosed that CMS viewed HHS policy as authorizing successor liability for CMPs. BP Care knew it was "affected," and it was a "provider" as soon as it assumed Barbara Parke's provider agreement in August 1999. Therefore, under the applicable law it was a party to the proceedings, unlike the plaintiff in *Buchanan*.

Finally, viewing the administrative scheme as BP Care's exclusive recourse does not preclude effective review because

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liability policy is not adequately enforced, the agency would be well-served by amending its regulations to address these issues.

[8] Whether BP Care had notice of the CMP proceedings forms the only factual issue in this case; therefore it is the only determination of the district court that we review for clear error. *See Cathedral Rock*, 223 F.3d at 358 (holding that the district court's findings of fact when ruling on a 12(b)(1) motion are reviewed for clear error).

the procedural posture of the agency adjudication permitted BP Care to seek agency review at each stage, even after the ALJ dismissed the proceedings. BP Care argues that after Barbara Parke withdrew its request for a hearing, BP Care was left in a procedural limbo in which it could not appeal to the DAB because no "hearing before an ALJ" had occurred. Appellant's Reply Br. at 7; *see* 42 C.F.R. § 498.5. But BP Care did have administrative appeal rights, even after Barbara Parke abandoned its hearing request.[9] A party may request review before the DAB of either an ALJ's decision or an ALJ's dismissal of a hearing request. 42 C.F.R. § 498.82. Further, a party may request that the ALJ vacate an order of dismissal at any time within sixty days of notice of the dismissal, and the ALJ must grant the request if the party shows good cause. *Id.* § 498.82. Therefore, participating in the proceedings prior to Barbara Parke's withdrawal of its hearing request was not BP Care's only option. After the ALJ dismissed the matter,[10] BP Care could have, as an "affected party," either requested DAB review of the ALJ's dismissal or moved the ALJ to vacate the dismissal.

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[9] It is possible that a business could assume a Medicare provider agreement before its predecessor has paid CMPs, but after its predecessor has exhausted all administrative remedies, as well as its right of appeal in a federal appeals court. We need not decide here whether a federal district court would have jurisdiction under 28 U.S.C. § 1331 to hear the successor's claim.

[10] The administrative record does not contain a notice of dismissal; however, the Secretary and BP Care agree that the ALJ dismissed the proceedings at Barbara Parke's motion. Appellee's Br. at 14; Appellant's Br. at 6. *See* 42 C.F.R. § 498.68(a) (providing that the ALJ may dismiss a hearing if an affected party withdraws its request).

III. Mandamus Jurisdiction

BP Care also seeks a writ of mandamus under 28 U.S.C. § 1361 nullifying the ALJ's conclusion that the automatic stay in bankruptcy does not apply to the CMP proceedings, *see* 11 U.S.C. § 362(a), and ordering the ALJ not to impose liability for the CMPs on BP Care. In order to justify mandamus jurisdiction, a plaintiff must show it has exhausted all other avenues of relief, and that the defendant owes the plaintiff a "clear nondiscretionary duty." *Heckler v. Ringer,* 466 U.S. 602, 616, 80 L. Ed. 2d 622, 104 S. Ct. 2013 (1984). Both the Supreme Court and this circuit have avoided deciding whether § 405(h) bars mandamus jurisdiction under 28 U.S.C. § 1361, in the same way that it bars jurisdiction under §§ 1331 and 1346. *See id; Mich. Ass'n of Homes & Servs. for the Aging, Inc. v. Shalala,* 127 F.3d 496, 503 (6th Cir. 1997).[11]

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[11] The literal wording of § 405(h) bars actions under 28 U.S.C. § 1331 or 1346. Before it was amended to its current form, § 405(h) barred actions under 28 U.S.C. § 41. *See Weinberger v. Salfi,* 422 U.S. 749, 756 n.3, 45 L. Ed. 2d 522, 95 S. Ct. 2457 (1975). Section 41 originally contained all of Title 28's grants of jurisdiction to United States district courts, save for several special-purpose grants of no relevance to the constitutionality of Social Security statutes. *Id.* In the 1948 recodification of title 28, a new chapter 85 was created to contain the jurisdictional grants to the district courts. Pursuant to the 1948 amendments, chapter 85 contained new sections 1331 through 1359 of title 28, which were formerly found in substance in the old § 41. In 1948, the mandamus statute was not included in chapter 85 because it had not been enacted yet. Chapter 85 of title 28 was amended in 1962 to include the mandamus statute.

In 1976, the Office of Law Revision Counsel "'revised' § 405(h) from its general bar of jurisdiction to its present form, which

The Supreme Court has, however, muted the importance of the question by holding in *Ringer* that a litigant who has a remedy available under § 405 has not met the exhaustion of remedies requirement for mandamus. 466 U.S. at 617; *see also Mich. Ass'n of Homes & Servs.*, 127 F.3d at 503. Thus, the *Ringer* decision has an effect similar to that of placing mandamus within § 405(h)'s jurisdictional bar. The

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seems to preclude only those actions 'brought under section 1331 or 1346 of title 28,' and not those actions brought under the other jurisdictional sections. . . ." *Bodimetric Health Svces., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 488 (7th Cir. 1990). In 1986, Congress adopted the codifier's language. *See id.* at 489 (citing Deficit Reduction Act of 1984, Pub. L. No. 98-369, 98 Stat. 494 (1984), § 2663(a)(4)(D)). At the same time, however, Congress specified that this "technical correction" was not to be "construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before [1986]." *Id.* (quoting Deficit Reduction Act § 2664(b)).

Since 28 U.S.C. § 1361 merely constituted an addition to the list of bases for district court jurisdiction which are found in title 28 and precluded *in toto* by § 405(h), and since the 1986 amendment to 42 U.S.C. § 405(h) was not intended to work a substantive change in the law, it is arguable, as a matter of statutory construction, that jurisdiction under 28 U.S.C. § 1361 is precluded by the third sentence of § 405(h). *Cf. Bodimetric Health Svces.*, 903 F.2d at 489 (applying this logic to conclude that § 405(h) bars diversity actions under 28 U.S.C. § 1332); *but see Ganem v. Heckler*, 241 U.S. App. D.C. 111, 746 F.2d 844, 851 (D.C. Cir. 1984) (finding that § 405(h) does not affect mandamus jurisdiction under § 1361 because if it did, the illogical result would follow that § 405(h) would bar mandamus in all lower federal courts except those in the District of Columbia, where lower courts' power to hear mandamus cases derives from an 1801 statute rather than from § 1361).

conclusion that the district court lacked jurisdiction over BP Care's claims under § 1331, because of BP Care's failure to present its claims to the agency and to exhaust administrative remedies, therefore applies equally to bar mandamus jurisdiction.

IV. Conclusion

For the foregoing reasons, we AFFIRM, on different grounds, the decision of the district court.

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

No. C-1-01-526

[Filed September 26, 2003]

BP CARE, INC.,
Plaintiff,

v.

TOMMY THOMPSON, Secretary, United States Department of Health and Human Services; et al,
Defendants.

OPINION

ORDER DENYING PLAINTIFF'S MOTION TO STRIKE AND GRANTING DEFENDANTS' MOTION TO DISMISS

This matter comes before the Court on Defendants' Motion to Dismiss Complaint and Cross-Claim, (Doc. # 15) and Plaintiff's Motion to Strike Defendant's Motion to Dismiss (Doc. # 18). Defendants Tommy Thompson and the

Department of Health and Human Services ("HHS"), collectively referred to as the Centers for Medicare and Medicaid Services ("CMS")[1] move pursuant to Federal Rule of Civil Procedure 12(b)(1) to dismiss this action on the ground that the Court lacks subject matter jurisdiction. Defendants alternatively move pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss the action on the ground that Plaintiff has failed to state a claim upon which relief can be granted. Plaintiff moves to strike Defendants' Motion to Dismiss on the grounds of violations of Local Rules and conversion of a Motion to Dismiss into a Motion for Summary Judgment. For the reasons set forth below, the Court denies Plaintiff's Motion to Strike and **GRANTS** the Defendants' Motion to Dismiss.

I. FACTUAL BACKGROUND

Plaintiff BP Care, Inc. ("BP Care") operates a skilled nursing facility formerly operated by West Chester Management Company, Inc., doing business as Barbara Parke Care Center ("Barbara Parke"). (Doc # 1 PP 2, 5.) BP Care and Barbara Parke are two separately incorporated entities. This action arises out of CMS' attempt to impose successor liability on BP Care for the civil money penalty imposed on the nursing home while operated under Barbara Parke.

The Medicare program is a federally funded and administered health insurance program for elderly and

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[1] The Department of Health and Human Services has delegated the administration of the Medicare Program to a subpart of the Department known as the Centers for Medicare and Medicaid Services.

disabled individuals. See 42 U.S.C. § 1395 et seq. ("Medicare Act"). Part A of the Medicare Act provides inpatient hospital insurance, including coverage of post-hospital nursing home stays. To be reimbursed for its services, a nursing home must enter into a provider agreement with the Secretary of HHS, and it must comply with various statutory requirements. See 42 U.S.C. § 1395cc(a). In order to enter a provider agreement, a nursing facility must undergo a comprehensive survey to ensure that it meets the health and safety requirements specified in the Medicare Act and CMS regulations. *See* 42 U.S.C. § 1395i-3(a)(3), (b)-(d). State and federal entities conduct surveys periodically thereafter to investigate continued compliance. *See* 42 U.S.C. § 1395i-3(g). If, pursuant to these surveys, the Secretary determines that the nursing home is not in compliance with health and safety requirements, he may impose a variety of remedies, including civil money penalties. *See* 42 U.S.C. § 1395i-3(h)(2)(B)(ii).

CMS imposed a civil money penalty on Barbara Parke after the Ohio Department of Health conducted a standard survey of the nursing home in February of 1999, prior to the nursing home's sale to BP Care, and determined that the facility was not in substantial compliance with health and safety requirements. (Doc. # 20 exh. 1.) If, as here, CMS decides to impose a civil money penalty on a nursing facility, it must send a written notice of the penalty to the facility stating, inter alia, the nature of the noncompliance, the statutory basis for the penalty, and "instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing ..." 42 C.F.R. § 488.434(a)(1), (2)(i), (ii), and (viii). A nursing facility may appeal the finding of noncompliance to the Civil Remedies Division of the Departmental Appeals Board of CMS ("DAB"). *See* 42 C.F.R. § 488.408(g)(1). The

nursing home has the right to request an evidentiary hearing before an administrative law judge ("ALJ"). See 42 C.F.R. § 498.40. CMS sent such notice to Barbara Parke, and in May of 1999 Barbara Parke appealed the survey's findings and imposition of the civil money penalty by requesting a hearing before an ALJ. (Doc. # 20, exh. 1.)

Around August of 1999, BP Care assumed operation of the nursing home and assumed Barbara Parke's Medicare provider agreement. (Doc. # 1 PP 22-23.) In September of 1999 Barbara Parke filed for bankruptcy and notified the government of its filing. (Doc. # 20 exh. 5.) CMS requested a stay of the administrative proceedings related to the civil money penalty while the nursing home considered whether to continue the proceedings in light of its bankruptcy. (*Id.* exh. 6.) The ALJ dismissed the case and remanded it to CMS in November of 1999 to consider new issues raised by the bankruptcy. (Id. exh. 7.) In January of 2001, finding no new issues raised by Barbara Parke's bankruptcy, the ALJ vacated his earlier Order to Dismiss and Remand (*Id.* exh. 11.) The bankruptcy trustee for Barbara Parke informed CMS that the attorney for BP Care would be in contact with CMS about the administrative hearing. (*Id.* exh. 12.) The parties provided no information indicating further correspondence between BP Care's representative and CMS or the ALJ. Barbara Parke's bankruptcy trustee withdrew its request for a hearing in May of 2001. With the request for hearing withdrawn, the ALJ dismissed the nursing home's appeal from CMS' survey findings. (*Id.* exh. 13). This dismissal constituted an end to the administrative proceedings, since an initial determination by CMS is binding unless it is reconsidered, revised, or reversed or modified by a hearing. *See* 42 C.F.R. § 498.20(b). Since no hearing took place, CMS' initial determination of noncompliance and imposition of a civil money penalty became binding.

CMS notified BP Care, the nursing home's new operator, that it would seek to recover from BP Care the civil money penalty incurred by the nursing home under Barbara Parke. (Doc. # 1 PP 34-35.) On August 3, 2001, Plaintiff BP Care filed this action seeking declaratory and injunctive relief. The parent company of BP Care filed a cross-claim in Barbara Parke's bankruptcy proceeding,[2] arguing that any claim CMS might have for offset, overpayment or recoupment for services rendered prior to the change of ownership be restricted to the bankruptcy estate of Barbara Parke. (Cross-Claim, p. 11, attached to Doc. # 5.) On May 1, 2002, this Court consolidated the King cross-claim with the instant action.

Defendants move to dismiss on the grounds that this Court lacks subject matter jurisdiction to hear the case and that Plaintiff fails to state a claim upon which relief can be granted. Plaintiff moves to strike on the grounds that (1) Defendants violated local procedural rules, and (2) Defendants attached exhibits to their Motion to Dismiss, thereby converting the Motion to Dismiss into a Motion for Summary Judgment.

II. STANDARDS OF REVIEW

The Defendants have moved to dismiss pursuant to Rules 12(b)(1) and 12(b)(6). "A motion to dismiss an action under Rule 12(b)(1) raises the question of the federal court's subject matter jurisdiction over the action." 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1350,

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[2] *In the Matter of Parke Care Center of Silverton, Inc., aka Deer Parke Care Center v. Roger King*, Bankruptcy Case 99-15041 through 99-15044, Adversary No. 00-1147.

at 194 (2d ed. 1990). On a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the plaintiff bears the burden of proving that the court does in fact have jurisdiction. *See generally RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134-35 (6th Cir. 1996);): *see also Rogers v. Stratton Indus.*, 798 F.2d 913, 915 (6th Cir. 1986). "When considering a motion to dismiss for lack of subject matter jurisdiction, this Court may look beyond jurisdictional allegations in the complaint and the Court may consider whatever evidence the parties submit." *Fairport Int'l. Exploration, Inc. v. Shipwrecked Vessel Known as The Captain Lawrence*, 105 F.3d 1078, 1081 (6th Cir. 1997), vacated on other grounds 523 U.S. 1091, 140 L. Ed. 2d 790, 118 S. Ct. 1558 (1998).

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of a complaint for "failure to state a claim upon which relief can be granted." In assessing the sufficiency of a complaint, courts must follow "the accepted rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957). This rule accords with the purpose of Rule 12(b)(6), which the Sixth Circuit has explained "is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complaint is true." *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993). Therefore, "on a Fed.R.Civ.P. 12(b)(6) motion, all of the allegations contained in the plaintiff's complaint are accepted as true, and the complaint is construed liberally in favor of the party opposing the motion." *Miller v. Currie*, 50 F.3d 373, 377 (6th Cir. 1995). At the same time, however, the Court "need not accept as true legal conclusions

or unwarranted factual inferences." *Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000).

A court generally cannot consider material beyond the pleadings in ruling on a Rule 12(b)(6) motion, but it may consider material that is properly submitted as part of the complaint. *Charal v. Royal Appliance Mfg. Co.*, 1995 U.S. App. LEXIS 24626, No. 94-3284, 1995 WL 490131, *2 (6th Cir. August 15, 1995) (materials integral to the complaint were considered on a Rule 12(b)(6) motion without converting the motion into one for summary judgment). Finally, "documents that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiffs complaint and are central to [the plaintiff's] claim." *Weiner v. Klais & Co.*, 108 F.3d 86, 89 (6th Cir., 1997). Plaintiff's Motion to Strike fails because the administrative record of the proceedings surrounding the imposition of the civil money penalty is just such a document, since Plaintiff refers to it in its Complaint, and Defendants have attached it to its Motion to Dismiss. Therefore, Defendants may attach the administrative record, as they have done under seal, without converting their Motion to Dismiss into a Motion for Summary Judgment.

III. ANALYSIS

BP Care's complaint makes two basic due process claims. First, BP Care claims that the administrative proceedings themselves were so flawed as to violate due process in that: (a) CMS did not serve an additional "right to hearing" notice on BP Care after the nursing facility changed ownership, and (b) the ALJ allowed Barbara Parke to withdraw the hearing request unilaterally. Second, BP Care claims that if administrative review is entirely unavailable, CMS' imposition of a prior operator's civil money penalty on the

new operator of the previously noncompliant facility violates due process.

A. DUE PROCESS - SUBJECT MATTER JURISDICTION

BP Care claims that Defendants have violated due process by their conduct in the administrative proceedings connected to the civil money penalty. BP Care cites Defendants' failure to issue an additional "right to hearing" notice to BP Care after the change in ownership of the nursing home and the ALJ's allowance of Barbara Parke's unilateral withdrawal of its hearing request as depriving BP Care of due process. BP Care asserts violations of the Medicare Act and Administrative Procedure Act in addition to violations of the Due Process Clause. Plaintiff also seeks declaratory relief from the ALJ's Order to Vacate Remand (*See* Doc. # 20 exh. 11) and a declaration that the "existing state of the Medicare laws, scheme, practices, and regulations ... deprive Plaintiff of its Due Process rights under the U.S. Constitution." (Doc. # 1 P3 of "Prayer for Relief".)

Judicial review of claims arising under the Medicare Act is tightly circumscribed by the Medicare Act's incorporation of a related provision of the Social Security Act, § 405(h), which "channels most, if not all, Medicare claims through this special review system" and "purports to make exclusive the judicial review method set forth in [1320a-7a(e)]." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8, 146 L. Ed. 2d 1, 120 S. Ct. 1084 (2000); *See also Cathedral Rock of N. Coll. Hill v. Shalala*, 223 F.3d 354, 359 (6th Cir. 2000); *Mich. Ass'n of Homes and Servs. For the Aging, Inc. v. Shalala*, 127 F.3d 496, 499 (6th Cir. 1997). Title 42 U.S.C. § 405 provides: "no findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or

governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." Section 1395ii makes § 405(h) applicable to the Medicare Act. Appeal of a determination that imposes a civil money penalty must be brought in the United States Court of Appeals. *See* 42 U.S.C. § 1320a-7a(e). Other decisions imposing non-monetary penalties imposed by CMS are reviewed in the district court. See 42 U.S.C. § 405(g).

Title 42 U.S.C. § 1320a-7a(e) is therefore the sole avenue of review of the imposition of civil money penalties and provides that:

> any person adversely affected by a determination of the Secretary under this section may obtain judicial review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside ... Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein ... No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of Title 28.

(emphasis added). In *Woodstock Care Center, Inc. v. Thompson*, 161 F. Supp. 2d 813, 815-16 (S.D. Ohio 2001), Chief Judge Rice concluded that the Sixth Circuit has exclusive jurisdiction to hear a challenge to a DAB decision imposing a civil money penalty. He examined both § 1320a-7a(e) and 42 C.F.R. § 498.90(a)(1), which provides that a DAB decision is final unless "the affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil monetary penalty, in a United States Court of Appeals ..." (emphasis added). This Court agrees that the language of § 1320a-7a(e) and the language of 42 C.F.R. § 498.90(a)(1) grant exclusive jurisdiction over review of the imposition of civil money penalties to the Court of Appeals.

BP Care contends that its claim is a constitutional due process claim and is thereby exempt from the review procedure designated for claims arising under the Medicare Act. BP Care asserts that it had no authority to intervene or join the administrative appeal because "the parties to the hearing are limited to the Secretary and the affected party" under 42 C.F.R. § 498.42. (Doc. # 19 at 10.) However, providers and prospective providers have administrative appeal rights under 42 C.F.R. § 498.5(c): "appeal rights of providers and prospective providers. Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision." 42 C.F.R. § 498.5(c). Here, Plaintiff became the provider when it assumed the provider agreement.

Next Plaintiff argues that it had no notice of the administrative proceedings. The Secretary had already issued a "right to hearing" notice to the provider when it alerted Barbara Parke to the pending imposition of the civil money

penalty. (Doc. # 1 P 21.) When the nursing facility changed ownership and BP Care assumed Barbara Parke's provider agreement, CMS served its motions in the administrative appeal on BP Care as well as on Barbara Parke. (Doc. # 20 exh. 10.) A plaintiff who did not avail itself of the administrative remedies at hand cannot circumvent the administrative review process by filing for review in district court by framing its claim as one arising under the Constitution rather than under the Medicare Act.

A claim "arises under" the Medicare Act "'when both the standing and the substantive basis for the presentation' of the claims" come from the Medicare Act. *Heckler v. Ringer*, 466 U.S. 602, 615, 80 L. Ed. 2d 622, 104 S. Ct. 2013 (1984) (*quoting Weinberger v. Salfi*, 422 U.S. 749, 760-61, 45 L. Ed. 2d 522, 95 S. Ct. 2457 (1975)). Attempting to challenge under the Due Process clause merely the "procedure" used by CMS and not the "substance" or merits of its decision will not surmount the § 405(h) barrier. The Supreme Court specifically rejected such an argument in Heckler v. Ringer: "The inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Id.* at 614-15 (*citing Mathews v. Eldridge*, 424 U.S. 319, 327, 47 L. Ed. 2d 18, 96 S. Ct. 893 (1976)). Plaintiffs have couched their claim in due process language but "it is apparent that plaintiff is challenging the defendants' conduct that led to the imposition of the civil monetary penalties; in other words, plaintiff's claim arises from the imposition of the monetary penalty." *Nursing Inn of Menlo Park v. California Department of Health*, 2003 U.S. Dist. LEXIS 5854, No. 02-1675, 2003 WL 1872961 at *5 (N.D. Cal. April 7, 2003). Judge Rice similarly found in Woodstock Care Center that the Sixth Circuit had exclusive jurisdiction to review constitutional arguments raised in the

context of a nursing home's specific challenge to the imposition of a civil money penalty. *See Woodstock Care Center*, 161 F. Supp. 2d at 817.

Plaintiff alleges violation of the Due Process Clause, the Medicare Act, and the Administrative Procedure Act and seeks relief from the existing state of the Medicare laws. This Court has no jurisdiction to hear these claims because all "arise under" the Medicare Act.

B. SUCCESSOR LIABILITY - FAILURE TO STATE A CLAIM

As a separate question, BP Care challenges the constitutionality of successor liability for a civil money penalty, entirely apart from the proceedings by which the civil money penalty was imposed. Plaintiff claims that Defendants deprive it of due process by imposing on it the civil money penalty of the prior nursing home operator and exposing BP Care to the risk of liability for overpayments connected to services rendered by the nursing home before its change of ownership.[3] According to BP Care, it had no opportunity to participate in administrative review of the civil money penalty and thus should not be liable to pay it. Taking all of Plaintiff's

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[3] The Court does not address Plaintiff's claim that liability for overpayments connected to pre-sale services should be limited to Barbara Parke's bankruptcy estate. Plaintiff has asserted no facts that indicate that such claims exist or are likely to occur, and the Government has represented that the Secretary has received and reviewed all claims for pre-sale services, rendered final decisions on pre-sale cost reports, collected resulting overpayments, and is not aware of circumstances that would cause him to reopen final determinations. (Doc. # 15 at 3.)

claims as true and construing Plaintiff's claim as a challenge merely to the constitutionality of imposing successor liability on a party completely isolated from administrative review, the Court may consider the claim as arising under the Due Process Clause within the meaning of 28 U.S.C. § 1331. *See Deerbrook Pavilion, LLC v. Shalala*, 235 F.3d 1100, 1102 (8th Cir. 2000). This due process claim is different from Plaintiff's due process claim discussed at section III(A) supra, because there Plaintiff asserted that Defendants' conduct and failure to perform certain actions in the administrative review proceedings by which a specific penalty was imposed deprived it of due process. Here Plaintiff asserts only that imputing liability to new operators of nursing homes for civil money penalties deprives it of due process. The first due process claim directly contests the administrative proceedings and the civil money penalty. The second due process claim contests whether successor liability can be imputed to BP Care at all.

The Court therefore turns to the merits of this claim. Had the administrative proceedings finished long before BP Care assumed Barbara Parke's provider agreement, CMS could still collect the civil money penalty from BP Care. Federal regulations provide that when a new operator of a nursing facility assumes the former operator's provider agreement after a change of ownership, that new owner assumes the agreement subject to the prior terms and conditions. Title 42 C.F.R. § 489.18 states that "an assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to ... (1) Any existing plan of correction. (2) Compliance with applicable health and safety standards ..." (emphasis added). The agency's own commentary on what burden an assigned agreement bears is clear: "[a] facility's prior compliance history should be considered regardless of

a change in ownership. A facility is purchased 'as is.'" 59 Fed. Reg. 56,116, 56,174 (1994). Finally, the federal regulations make explicit: "[a] facility may not avoid a remedy on the basis that it underwent a change of ownership." 42 C.F.R. § 488.414(d)(3)(I).

The Eighth Circuit considered the argument here asserted by BP Care in *Deerbrook Pavilion, LLC v. Shalala*. In Deerbrook Pavilion, a new operator of a nursing facility assumed the previous operator's provider agreement, an agreement subject to a civil money penalty. Following the lead of the Fifth Circuit's decision in *United States v. Vernon Home Health, Inc.*, 21 F.3d 693 (5th Cir. 1994),[4] the Eighth Circuit held that new operators assuming provider agreements subject to civil money penalties are liable to pay them. 235 F.3d at 1104.

A new operator is not required to assume the provider agreement of the former operator. *See Vernon Home Health*, 21 F.3d at 696 ("[the new operator] could have chosen not to accept the automatic assignment of the provider agreement"); *Livingston Care Center, Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("participation in the Medicare program is a voluntary undertaking"). To ensure freedom from liability for penalties incurred by the prior operator, a new operator

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[4] The Fifth Circuit held that a new operator assuming a former operator's provider agreement was jointly and severally liable with the old owner for Medicare overpayments. *See United States v. Vernon Home Health, Inc.*, 21 F.3d 693, 696 (5th Cir. 1994). The Eighth Circuit held that the situation in *Vernon* was indistinguishable from that of *Deerbrook*: both imposed monetary liabilties. Following Vernon's logic, the Eighth Circuit held *Deerbrook* to be liable for the civil money penalty under 42 C.F.R. § 489.18(d) (2000). *See Deerbrook Pavilion*, 235 F.3d at 1104.

could apply for a new provider agreement. This would require a new application process, however, and the continuous operation of the nursing home during the change in ownership might be disturbed while the new operator awaited certification. Many new operators therefore assume their predecessor's provider agreement. Simply assuming the provider agreement, however, exposes the new operator to any liability incurred under the agreement because a facility is purchased "as is." *See* 59 Fed. Reg. 56,174 (1994). Because the new operator retains the compliance history - good or bad - of the provider agreement, it is necessary for operators to investigate the compliance history of the nursing facility. Surveys of nursing facilities are available to the public, *see* 42 U.S.C. § 1395i-3(g)(5)(A).

Because a facility cannot evade a plan of correction merely by changing ownership, and because an assigned agreement is subject to existing plans of correction, a new operator is liable for both the assets and liabilities of the provider agreement. Savvy purchasers likely take these liabilities into consideration when negotiating a purchase price. As the Eighth Circuit noted, "surveys of facilities are matters of public record ... and checking a facility's regulatory history is an important due diligence task." *Deerbrook Pavilion*, 235 F.3d at 1105. When BP Care assumed Barbara Parke's provider agreement, it assumed that provider's assets and liabilities. CMS thus has authority to impose the civil money penalty on BP Care, regardless of whether *BP Care* had access to administrative review. BP Care therefore states no claim upon which relief can be granted.

IV. CONCLUSION

This Court has no jurisdiction to consider Defendants' actions in imposing the civil money penalty on BP Care because the district court is the improper forum in which to file such a challenge. This Court has subject matter jurisdiction to consider the legal challenge to the issue of successor liability, but Plaintiff has stated no claim upon which relief can be granted. The Court therefore denies Plaintiff's Motion to Strike and **GRANTS** Defendant's Motion to Dismiss. (Doc. # 15).

IT IS SO ORDERED.

/s/Susan J. Dlott

United States District Judge

APPENDIX D

42 CFR § 483.5 Definitions.

(a) Facility defined. For purposes of this subpart, facility means a skilled nursing facility (SNF) that meets the requirements of sections 1819(a), (b), (c), and (d) of the Act, or a nursing facility (NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. "Facility" may include a distinct part of an institution (as defined in paragraph (b) of this section and specified in § 440.40 and § 440.155 of this chapter), but does not include an institution for the mentally retarded or persons with related conditions described in § 440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity that participates in the program, whether that entity is comprised of all of, or a distinct part of, a larger institution. For Medicare, an SNF (see section 1819(a)(1) of the Act), and for Medicaid, an NF (see section 1919(a)(1) of the Act) may not be an institution for mental diseases as defined in § 435.1009 of this chapter.

(b) Distinct part --

(1) Definition. A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or

designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term "distinct part" also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section.

(2) Requirements. In addition to meeting the participation requirements for long-term care facilities set forth elsewhere in this subpart, a distinct part SNF or NF must meet all of the following requirements:

(i) The SNF or NF must be operated under common ownership and control (that is, common governance) by the institution of which it is a distinct part, as evidenced by the following:

(A) The SNF or NF is wholly owned by the institution of which it is a distinct part.

(B) The SNF or NF is subject to the by-laws and operating decisions of a common governing body.

(C) The institution of which the SNF or NF is a distinct part has final responsibility for the distinct part's administrative decisions and personnel policies, and final approval for the distinct part's personnel actions.

(D) The SNF or NF functions as an integral and subordinate part of the institution of which it is a distinct part, with significant common resource usage of buildings, equipment, personnel, and services.

(ii) The administrator of the SNF or NF reports to and is directly accountable to the management of the institution of which the SNF or NF is a distinct part.

(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly accountable to the management of the institution of which it is a distinct part.

(iv) The SNF or NF is financially integrated with the institution of which it is a distinct part, as evidenced by the sharing of income and expenses with that institution, and the reporting of its costs on that institution's cost report.

(v) A single institution can have a maximum of only one distinct part SNF and one distinct part NF.

(vi) (A) An institution cannot designate a distinct part SNF or NF, but instead must submit a written request with documentation that demonstrates it meets the criteria set forth above to CMS to determine if it may be considered a distinct part.

(B) The effective date of approval of a distinct part is the date that CMS determines all requirements (including enrollment with the fiscal intermediary (FI)) are met for approval, and cannot be made retroactive.

(C) The institution must request approval from CMS for all proposed changes in the number of beds in the approved distinct part.

(c) Composite distinct part -- (1) Definition. A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as defined in § 413.65(a)(2) of this chapter.

(2) Requirements. In addition to meeting the requirements of paragraph (b) of this section, a composite distinct part must meet all of the following requirements:

(i) A SNF or NF that is a composite of more than one location will be treated as a single distinct part of the institution of which it is a distinct part. As such, the composite distinct part will have only one provider agreement and only one provider number.

(ii) If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of public monies without sacrificing the quality of care.

(iii) If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.

(iv) To ensure quality of care and quality of life for all residents, the various components of a composite distinct part must meet all of the requirements for participation independently in each location.

42 CFR § 488.432 Civil money penalties: When a penalty is collected.

(a) When facility requests a hearing.

(1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

(i) Section 498.40 of this chapter for a

(A) SNF;

(B) Dually participating facility;

(C) State-operated NF; or

(D) Non-State operated NF against which CMS is imposing remedies.

(ii) Section 431.153 of this chapter for a non-State operated NF that is not subject to imposition of remedies by CMS.

(2) (i) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance

after the facility achieves substantial compliance or is terminated.

(ii) If a facility requests a hearing for a civil money penalty imposed per instance of noncompliance within the time specified in paragraph (a)(1) of this section, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance.

(b) When a facility does not request a hearing for a civil money penalty imposed per day. (1) If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the facility --

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) When a facility does not request a hearing for a civil money penalty imposed per instance of noncompliance. If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the time frame for requesting a hearing expires.

(c) When a facility waives a hearing. (1) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when the facility --

(i) Achieves substantial compliance; or (ii) Is terminated.

(2) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per instance of noncompliance, CMS or the State initiates collection of the penalty upon receipt of the facility's notification.

(d) Accrual and computation of penalties for a facility that--

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

(e) The collection of civil money penalties is made as provided in § 488.442.

42 CFR § 488.434 Civil money penalties: Notice of penalty.

(a) CMS notice of penalty. (1) CMS sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) Content of notice. The notice that CMS sends includes--

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;

(vi) When the penalty stops accruing, if applicable;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) State notice of penalty. (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must --

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

42 CFR § 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) Waiver of a hearing. The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) Reduction of penalty amount. (1) If the facility waives its right to a hearing in accordance with the procedures

specified in paragraph (a) of this section, CMS or the State reduces the civil money penalty amount by 35 percent.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

42 CFR § 488.438 Civil money penalties: Amount of penalty.

(a) Amount of penalty -- (1) Per day penalties. The per day penalties are within the following ranges, set at $50 increments:

(i) Upper range -- $3,050 - $10,000. Penalties in the range of $3,050 - $10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(ii) Lower range -- $50 - $ 3,000. Penalties in the range of $50 - $3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(2) Per instance penalty. When penalties are imposed for an instance of noncompliance, the penalties will be in the range of $1,000-$10,000 per instance.

(b) Basis for penalty amount. The amount of penalty is based on CMS's or the State's assessment of factors listed in paragraph (f) of this section.

(c) Decreased penalty amounts. Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, CMS or the State will shift the penalty amount imposed per day to the lower range.

(d) Increased penalty amounts. (1) Before a hearing requested in accordance with § 488.432(a), CMS or the State may propose to increase the per day penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) CMS does and the State must increase the per day penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) Review of the penalty. When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not --

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) Factors affecting the amount of penalty. In determining the amount of penalty, CMS does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) The facility's degree of culpability. Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

42 CFR § 489.11 Acceptance of a provider as a participant.

(a) Action by CMS. If CMS determines that the provider meets the requirements, it will send the provider --

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) Action by provider. If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged

insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) Notice of acceptance. If CMS accepts the agreement, it will return one copy to the provider with a written notice that --

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.

42 CFR § 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) What constitutes change of ownership -- (1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.

(3) Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) Leasing. The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) Notice to CMS. A provider who is contemplating or negotiating a change of ownership must notify CMS.

(c) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) Conditions that apply to assigned agreements. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Compliance with applicable health and safety standards.

(3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.

(4) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(e) Effect of leasing. The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

42 CFR § 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on

technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing nonwaived testing;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Facility administration and quality systems standards.

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

42 CFR § 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e) [Removed and reserved. See 61 FR 32347, 32349, June 24, 1996.]

(f) [Removed and reserved. See 61 FR 32347, 32349, June 24, 1996.]

(g) Although § 1866(h) of the Act is silent regarding appeal rights for suppliers and practitioners, the rules in this

part include procedures for review of determinations that affect those two groups.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act --

(l) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act --

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.

42 CFR § 498.2 Definitions.

As used in this part --

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and "party" means the affected party or CMS (or the OIG), as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

OIG stands for the Department's Office of the Inspector General.

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), hospice, or religious nonmedical health care institution (RNHCI) that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and prospective provider means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

Supplier means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), Federal qualified health center (FQHC), ambulatory surgical center (ASC), organ procurement organization (OPO), an entity approved by CMS to furnish outpatient diabetes self-management training, or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services, and prospective supplier means any of the listed entities that seeks to be approved for coverage of its services under Medicare. However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term "supplier" has the meaning specified in § 1001.2 of this title.

42 CFR § 498.3 Scope and applicability.

(a) Scope. (1) This part sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(2) The determinations listed in this section affect participation in the Medicare program. Many of the procedures of this part also apply to other determinations that do not affect participation in Medicare. Some examples follow:

(i) CMS's determination to terminate an NF's Medicaid provider agreement.

(ii) CMS's determination to cancel the approval of an ICF/MR under section 1910(b) of the Act.

(iii) CMS's determination, under the Clinical Laboratory Improvement Act (CLIA), to impose alternative sanctions or to suspend, limit, or revoke the certificate of a laboratory even though it does not participate in Medicare.

(3) The following parts of this chapter specify the applicability of the provisions of this part 498 to sanctions or remedies imposed on the indicated entities:

(i) Part 431, subpart D -- for nursing facilities (Nfs).

(ii) Part 488, subpart E (§ 488.330(e)) -- for SNFs and Nfs.

(iii) Part 493, subpart R (§ 493.1844) -- for laboratories.

(b) Initial determinations by CMS. CMS makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under § 413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under § 413.65 of this chapter.

(3) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(4) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(5) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(6) Whether the services of a supplier continue to meet the conditions for coverage.

(7) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(8) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(9) CMS's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(10) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(11) Whether to deny payment under § 409.19 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(12) [Reserved]

(13) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy

specified in § 488.406 of this chapter, except the State monitoring remedy.

(14) The level of noncompliance found by CMS in a SNF or NF but only if a successful challenge on this issue would affect --

(i) The range of civil money penalty amounts that CMS could collect (The scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter); or

(ii) A finding of substandard quality of care that results in the loss of approval for a SNF or NF of its nurse aide training program.

(15) The effective date of a Medicare provider agreement or supplier approval.

(16) The finding of substandard quality of care that leads to the loss by a SNF or NF of the approval of its nurse aide training program.

(c) Initial determinations by the OIG. The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) Administrative actions that are not initial determinations. Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution --

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF – (i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by CMS as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

(e) Exclusion of civil rights issues. The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

42 CFR § 498.4 NFs subject to appeals process in part 498.

A NF is considered a provider for purposes of this part when it has in effect an agreement to participate in Medicaid, including an agreement to participate in both Medicaid and Medicare and it is a --

(a) State-operated NF; or

(b) Non State-operated NF that is subject to compliance action as a result of --

(1) A validation survey by CMS; or

(2) CMS's review of the State's survey findings.

42 CFR § 498.5 Appeal rights.

(a) Appeal rights of prospective providers.

(1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a)."

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under§ 498.30, is entitled to a hearing before an ALJ.

(b) Appeal rights of providers. Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) Appeal rights of providers and prospective providers. Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision.

(d) Appeal rights of prospective suppliers. (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) Appeal rights of suppliers. Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) Appeal rights of suppliers and prospective suppliers.

(1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) Appeal rights for certain practitioners. A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the

requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) Appeal rights for nonparticipating hospitals that furnish emergency services. A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) Appeal rights for suspended or excluded practitioners, providers, or suppliers. (1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with § 498.3(c)(2), or has been sanctioned in accordance with § 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Departmental Appeals Board review and has a right to seek judicial review of the Board's decision by filing an action in Federal district court.

(j) Appeal rights for Medicaid ICFs/MR terminated by CMS.

(1) Any Medicaid ICF/MR that has had its approval cancelled by CMS in accordance with § 498.3(b)(8) has a right to a hearing before an ALJ, to request Departmental Appeals Board review of the hearing decision, and to seek judicial review of the Board's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless CMS --

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

(k) Appeal rights of NFs. Under the circumstances specified in § 431.153 (g) and (h) of this chapter, an NF has a right to a hearing before an ALJ, to request Board review of the hearing decision, and to seek judicial review of the Board's decision.42 CFR 498.10

42 CFR § 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with CMS, the ALJ, or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

42 CFR § 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party--

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

42 CFR § 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

42 CFR 498.15 § 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

42 CFR § 498.17 Filing of briefs with the ALJ or Departmental Appeals Board, and opportunity for rebuttal.

(a) Filing of briefs and related documents. If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) Opportunity for rebuttal. (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

42 CFR § 498.20 Notice and effect of initial determinations.

(a) Notice of initial determination--(1) General rule. CMS or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) Special rules: Independent laboratories and suppliers of portable x-ray services. If CMS determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice--

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) Special rules: Nonparticipating hospitals that elect to claim payment for emergency services. If CMS determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice--

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) Other special rules. Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of

additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X--for rural health clinics.
Part 416--for ambulatory surgical centers.
Part 489--for providers, when their provider agreements have been terminated.
Part 1001, Subpart B--for excluded or suspended providers, suppliers, physicians, or practitioners.
Part 1001, Subpart C--for providers, when their provider agreements are terminated by the OIG.
Part 1004--for sanctioned providers and practitioners.

(b) Effect of initial determination. An initial determination is binding unless it is--

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

42 CFR § 498.22 Reconsideration.

(a) Right to reconsideration. CMS reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. (None of the determinations made by the OIG are subject to reconsideration.)

(b) Request for reconsideration: Manner and timing. The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request--

(1) With CMS or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) Content of request. The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) Extension of time to file a request for reconsideration. (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with CMS, stating the reasons why the request was not filed timely.

(2) CMS will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

42 CFR § 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before CMS

mails the notice of reconsidered determination, and CMS approves the withdrawal request.

42 CFR § 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, CMS--

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

42 CFR § 498.25 Notice and effect of reconsidered determination.

(a) Notice. (1) CMS mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the

affected party fails to meet, and informs the party of its right to a hearing.

(b) Effect. A reconsidered determination is binding unless--

(1) CMS or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

42 CFR § 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. CMS or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

42 CFR § 498.32 Notice and effect of reopening and revision.

(a) Notice. (1) CMS or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to

which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) Effect. A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) CMS or the OIG further revises the revised determination.
42 CFR 498.40

42 CFR § 498.40 Request for hearing.

(a) Manner and timing of request.

(1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with CMS or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with § 498.22(b)(3)).

(b) Content of request for hearing. The request for hearing must--

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) Extension of time for filing a request for hearing. If the request was not filed within 60 days--

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

42 CFR § 498.42 Parties to the hearing.

The parties to the hearing are the affected party and CMS or the OIG, as appropriate.

42 CFR § 498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.
42 CFR 498.45

42 CFR § 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

42 CFR § 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

42 CFR § 498.48 Notice of prehearing conference.

(a) Timing of notice. The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) Content of notice. The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) Additional issues. Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if---

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

42 CFR § 498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

42 CFR § 498.50 Record, order, and effect of prehearing conference.

(a) Record of prehearing conference. (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) Order and opportunity to object. (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) Effect of prehearing conference. The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

42 CFR § 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

42 CFR § 498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

42 CFR § 498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and

place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the preceedings is made and a separate decision issued with respect to each affected party.

42 CFR § 498.56 Hearing on new issues.

(a) Basic rules. (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) Time limits. The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act--

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) Notice and conduct of hearing on new issues. (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) Remand to CMS or the OIG. At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to CMS or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS or the OIG to return the case to the ALJ for further proceedings.

42 CFR § 498.58 Subpoenas.

(a) Basis for issuance. The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) Timing of request by a party. The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) Content of request. The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) Method of issuance. Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

42 CFR § 498.60 Conduct of hearing.

(a) Participants in the hearing. The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) Hearing procedures. (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(c) Scope of review: Civil money penalty. In civil money penalty cases --

(1) The scope of review is as specified in § 488.438(e) of this chapter; and

(2) CMS's determination as to the level of noncompliance of an SNF or NF must be upheld unless it is clearly erroneous.

42 CFR § 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

(b) [Removed. See 61 FR 32347, 32350, June 24, 1996.]

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare Hospital Insurance)

42 CFR § 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

42 CFR § 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

42 CFR § 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

42 CFR § 498.66 Waiver of right to appear and present evidence.

(a) Waiver procedures. (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) Effect of waiver. If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS or the OIG shows good cause for requiring the presentation of oral evidence.

(c) Dismissal for failure to appear. If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) Hearing without oral testimony. When there is no oral testimony, the ALJ will–

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Fu nish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

42 CFR § 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

42 CFR § 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative--

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a "show cause" notice, with a showing of good cause.

42 CFR § 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) Res judicata. There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or

issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) No right to hearing. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) Hearing request not timely filed. The affected party did not file a hearing request timely and the time for filing has not been extended.

42 CFR § 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

42 CFR § 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with § 498.22(b)(3).)

42 CFR § 498.74 Administrative Law Judge's decision.

(a) Timing, basis and content. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) Notice and effect. A copy of the decision is mailed to the parties and is binding on them unless --

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 498.82, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

42 CFR § 498.76 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

42 CFR § 498.78 Remand by the Administrative Law Judge.

(a) If CMS or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS or the OIG for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

42 CFR § 498.80 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

42 CFR § 498.82 Request for Departmental Appeals Board review.

(a) Manner and time of filing. (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting

party, extends the time for filing. The rules set forth in § 498.40(c) apply to extension of time for requesting Departmental Appeals Board review. (The date of receipt of notice is determined in accordance with § 498.22(c)(3).)

(b) Content of request for review. A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

42 CFR § 498.83 Departmental Appeals Board action on request for review.

(a) Request by CMS or the OIG. The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS or the OIG for review of an ALJ decision or dismissal.

(b) Request by the affected party. The Board will grant the affected party's request for review unless it dismisses the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) Effect of dismissal. The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) Review panel. If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Board, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S Public Health Service.

42 CFR § 498.85 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 498.17.

42 CFR § 498.86 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record --

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

42 CFR § 498.88 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision –

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

42 CFR § 498.90 Effect of Departmental Appeals Board Decision

(a) General rule. The Board's decision is binding unless --

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 498.102.

(b) Right to judicial review. Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) Special rules: Civil money penalty.

(1) Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

(2) Timing for collection of civil money penalty. For SNFs and NFs, the rules that apply are those set forth in subpart F of part 488 of this chapter.

42 CFR § 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Board's decision (as determined under § 498.22(c)(3)), unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

42 CFR § 498.100 Basis, timing, and authority for reopening an ALJ or Board decision.

(a) Basis and timing for reopening. An ALJ of Departmental Appeals Board decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) Authority to reopen. (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

42 CFR § 498.102 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board --

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance --

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) Basis for revised decision and right to review. (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

42 CFR § 498.103 Notice and effect of revised decision.

(a) Notice. The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) Effect -- (1) ALJ revised decision. An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) Departmental Appeals Board revised decision. A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

42 CFR § 1000.10 General definitions.

In this chapter, unless the context indicates otherwise --

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

Directly, as used in the definition of "furnished" in this section, means the provision of items and services by individuals or entities (including items and services provided by them, but manufactured, ordered or prescribed by another individual or entity) who submit claims to Medicare, Medicaid or other Federal health care programs.

ESRD stands for end-stage renal disease.

FR stands for Federal Register.

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to

providers, practitioners or suppliers who submit claims to these programs for such items or services.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Indirectly, as used in the definition of "furnished" in this section, means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.

Inspector General means the Inspector General for Health and Human Services.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

QIO stands for Utilization and Quality Control Quality Improvement Organization.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

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(2)

No. 05-167

In the Supreme Court of the United States

BP CARE, INC., PETITIONER

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether a Medicare provider operating a skilled nursing facility must exhaust administrative remedies before seeking judicial review of a civil money penalty determination.

2. Whether the Secretary violated procedural due process by holding petitioner liable for a civil money penalty imposed against petitioner's predecessor-in-interest where petitioner had, but failed to avail itself of, an opportunity to contest the penalty in an administrative hearing.

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In the Supreme Court of the United States

No. 05-167

BP CARE, INC., PETITIONER

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 3a-24a) is reported at 398 F.3d 503. The opinion of the district court (Pet. App. 25a-40a) is reported at 337 F. Supp. 2d 1021.

JURISDICTION

The judgment of the court of appeals was entered on February 15, 2005. A petition for rehearing was denied on May 3, 2005 (Pet. App. 1a-2a). The petition for a writ of certiorari was filed on July 28, 2005. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Medicare, established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, is a feder-

ally subsidized health insurance program for the elderly and certain disabled people. 42 U.S.C. 1395c, 1395d. Part A of the program provides insurance for covered inpatient hospital and related post-hospital services, including skilled nursing care. 42 U.S.C. 1395f(b)(1), 1395x(h), 1395x(v)(1). To receive payment for services provided to Medicare beneficiaries, a skilled nursing facility must enter into a provider agreement with the Secretary of Health and Human Services, 42 U.S.C. 1395cc(a), and meet statutory standards relating to beneficiary health, safety, and care, 42 U.S.C. 1395i-3(a) to (d).

The Medicare Act sets forth detailed procedures for the inspection of skilled nursing facilities and the enforcement of health and safety standards. Each skilled nursing facility is subject to a standard survey that must be conducted without prior notice. 42 U.S.C. 1395i-3(g)(2)(A). The survey must examine, for a sample of residents, the quality of care furnished individual patients and the facility's compliance with statutory provisions protecting each resident's right to choose his or her attending physician, to be free from physical or chemical restraint, and to exercise other individual rights guaranteed by statute. 42 U.S.C. 1395i-3(g)(2)(A)(ii).

Congress authorized the Secretary to impose a broad range of remedies to correct violations uncovered in surveys and to ensure compliance with statutory standards of care. The Secretary is thus empowered to direct a plan for correcting statutory violations, to deny further reimbursement for services rendered after the deficiency is discovered, to appoint temporary management, to terminate a facility's right to participate in Medicare, to transfer residents and close the facility, and to impose

civil money penalties. 42 U.S.C. 1395i-3(h); 42 C.F.R. 488.406, 488.408(b)-(e).

A provider that is dissatisfied with the imposition of one of the above remedies has a right to an administrative hearing to contest the underlying finding of a statutory or regulatory deficiency. 42 U.S.C. 1395i-3(h)(2)(B)(ii); 1395cc(h); 42 C.F.R. 498.3(b)(13) and (14); *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 7-8 (2000). Implementing regulations afford the provider an opportunity to appear before an administrative law judge (ALJ), to be represented by counsel, to call witnesses, and to present other evidence. 42 C.F.R. 498.40 to 498.78. Hearing decisions must be in writing and set forth the reasons for the enforcement action as well as the evidence on which it is based. 42 C.F.R. 498.74.

Special notice and review procedures further apply to the imposition of a civil money penalty. When the Secretary imposes a civil money penalty, he must send written notice to the facility that identifies, among other matters, the nature of the violation, the statutory basis for the penalty, the amount of the penalty, the factors considered in determining the amount of the penalty, and the provider's right either to request an administrative hearing or to accept the penalty and receive a 35% reduction in the amount due. 42 C.F.R. 488.434(a), 488.436. If a hearing is requested, any party that is dissatisfied with the ALJ's hearing decision may request further administrative review before HHS's Departmental Appeals Board. 42 C.F.R. 498.82. An Appeals Board ruling concerning the imposition of a civil money penalty constitutes the Secretary's final administrative decision. 42 C.F.R. 498.88(c).

Any person adversely affected by a final administrative decision imposing a civil money penalty may obtain judicial review of the Secretary's determination by filing a petition in the appropriate court of appeals within 60 days. 42 U.S.C. 1395i-3(h)(2)(B)(ii) (incorporating by reference 42 U.S.C. 1320a-7a(e)). Judicial review of a civil money penalty determination is further subject to the limitations of 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, which provides that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided," and that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." 42 U.S.C. 405(h); see also 42 U.S.C. 1320a-7(f)(3) (applying Section 405(h) to the provisions for reviewing civil money penalty determinations under 42 U.S.C. 1320a-7a).

2. This case arises out of the imposition of a civil money penalty on the Barbara Parke Care Center, a skilled nursing facility located in Middletown, Ohio. A survey had found that the facility did not meet Medicare requirements concerning quality of care, quality of life, provision of services, and staff treatment of patients. The Secretary notified the facility that Medicare intended to impose a $35,650 civil penalty on account of these deficiencies and informed the facility of its right to request an administrative hearing. The facility challenged the validity of each underlying charge and, on April 30, 1999, requested a hearing before an ALJ. Pet. App. 5a.

At the time of the hearing request, the facility was operated by the West Chester Management Company,

Inc., an Ohio corporation doing business under the name Barbara Parke Care Center. Pet. App. 4a, 28a. In August 1999, while the administrative review proceedings were pending, however, West Chester assigned its lease of the nursing facility and its Medicare provider agreement to petitioner. That assignment permitted petitioner to use Barbara Parke Care Center's provider number and to continue to receive Medicare reimbursement for the nursing home without interruption. Petitioner was incorporated and represented by the same attorney, Geoffrey E. Webster, who had represented Barbara Parke Care Center. *Id.* at 5a.

On September 13, 1999, West Chester commenced proceedings in bankruptcy. Pet. App. 6a. Beginning in January 2000, the Secretary served motions on petitioner in the administrative proceedings disclosing the Secretary's view that petitioner would be liable for any civil money penalty imposed on the provider. *Id.* at 20a. In May 2001, West Chester's bankruptcy trustee withdrew its request for an administrative hearing on the civil money penalty, *id.* at 7a, and petitioner's counsel, Webster, was served with the trustee's withdrawal request, C.A. J.A. 325.

Petitioner did not seek to continue the administrative proceedings commenced by West Chester and did not otherwise administratively contest the civil money penalty, even though it knew it could be held liable for the penalty as a successor under established Medicare policy. Pet. App. 20a. Medicare regulations provide that an assigned provider agreement remains subject to all applicable statutes and regulations and the terms and conditions under which the agreement was originally issued, including, but not limited to, the obligation to implement an existing plan for correcting known defi-

ciencies and to comply with applicable health and safety standards. 42 C.F.R. 489.18. The regulations further provide that "[a] facility may not avoid a remedy on the basis that it underwent a change of ownership." 42 C.F.R. 488.414(d)(3)(i). Thus, as HHS explained in promulgating the regulations, generally "when a change of ownership occurs, all Medicare penalties and sanctions are automatically assigned to the new owner or owners." 59 Fed. Reg. 56,204 (1994). Medicare policy accordingly provides that a civil money penalty "runs with" the provider agreement authorizing the participation of a skilled nursing facility in the Medicare program. Successors-in-interest who assume the prior operator's provider agreement are therefore jointly and severally liable for penalties imposed on their predecessors. Centers for Medicare & Medicaid Services, Dep't of Health & Human Servs., State Operations Manual § 3210E (2004); *Deerbrook Pavilion, LLC* v. *Shalala*, 235 F.3d 1100, 1104 (8th Cir. 2000), cert. denied, 534 U.S. 992 (2001).

Petitioner, as West Chester's successor-in-interest and the assignee of West Chester's Medicare provider agreement, was thus potentially liable for the civil money penalty imposed during West Chester's operation of the facility. As discussed, petitioner did not seek further administrative review of the proposed civil money penalty. The ALJ therefore dismissed the administrative appeal instituted by West Chester and the Secretary's initial determinations of noncompliance and imposition of a civil money penalty on the Barbara Parke facility became final. Pet. App. 28a.

3. Petitioner subsequently filed a civil action against the Secretary in federal district court. Petitioner alleged that the imposition of a civil money penalty with-